UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE NEW YORK TIMES COMPANY, and SHEILA KAPLAN,	:	
Plaintiffs,	:	**COMPLAINT**
- against -	:	
U.S. FOOD AND DRUG ADMINISTRATION,	:	
Defendant.	:	

Plaintiffs THE NEW YORK TIMES COMPANY and SHEILA KAPLAN, by their undersigned attorneys, allege for their Complaint:

1. This is an action under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), to obtain an order for the production of agency records from the U.S. Food and Drug Administration ("FDA") in response to requests properly made by Plaintiffs (jointly, "The Times").

PARTIES

2. Plaintiff The New York Times Company publishes *The New York Times* newspaper and www.nytimes.com. The New York Times Company is headquartered in this judicial district at 620 Eighth Avenue, New York, New York.

3. Plaintiff Sheila Kaplan is a reporter for *The New York Times* newspaper and an employee of The New York Times Company.

4. Defendant FDA is an agency of the federal government that has possession and control of the records that Plaintiffs seek.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

6. Venue is premised on the place of business of Plaintiffs and is proper in this district under 5 U.S.C. § 552(a)(4)(B).

7. Plaintiffs have exhausted all administrative remedies available in regard to the requests at issue. *See* U.S.C. § 552(a)(6)(C).

FACTS

The June 2018 Request

8. In June of 2018, The Times submitted a FOIA request (the "June 2018 Request") to the FDA for documents related to Juul Labs, Inc. ("Juul"). This Request seeks "a copy of all materials that are submitted in any form, to the FDA, from JUUL or its representatives, lawyers, lobbyists, and other parties" in response to an April 24, 2018, letter from the FDA (https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM605490.pdf).

9. On June 25, 2018, the FDA acknowledged receipt of the June 2018 Request.

10. On July 10, 2018, the FDA's Center for Tobacco Products ("CTP") indicated that it had received the June 2018 Request on July 6, 2018, and that it would conduct a search for responsive records.

11. On November 14, 2018, the CTP issued a letter to The Times regarding the June 2018 Request. The letter stated that the agency found that responsive records "may contain information that FOIA Exemption 4 prohibits from release as trade secrets and/or confidential commercial information." The letter also stated that pursuant to Executive Order 12600 and 21 C.F.R. § 20.61(e)(1), the FDA was required to provide Juul with "predisclosure notification" of the request. As the letter noted, a submitter typically has "5 working days from receipt of [the agency's] notice to object to disclosure of any part of the records and state all bases for its objections." Because of "the large volume of records" in this case, however, the FDA instructed Juul "to follow a response schedule that extends through April."

12. The FDA has not since communicated with The Times regarding the June 2018 Request.

The October 2018 Request

13. In October of 2018, The Times submitted a second request to the FDA regarding Juul (the "October 2018 Request"). This Request seeks "[m]arketing and advertising records and sales strategy records" that the FDA seized from the offices of Juul in September 2018. *See* Jan Hoffman, *F.D.A. Seizes Documents from Juul Headquarters*, New York Times (Oct. 2, 2018), https://nyti.ms/2QuffA3.

14. On November 28, 2018, the FDA denied the October 2018 Request, citing FOIA Exemption 7(A) (5 U.S.C. § 552(b)(7)(A)) and related regulations.

15. On January 24, 2019, The Times appealed the FDA's denial of the October 2018 Request to the U.S. Department of Health and Human Services ("HHS"). The Times contended that the FDA cannot rely on Exemption 7(A) because it made no showing that

the release of any records sought – let alone all of them – could reasonably be expected to interfere with an enforcement proceeding.

16. The HHS has not made a determination regarding The Times's administrative appeal of the denial of the October 2018 Request.

COUNT I

17. Plaintiffs repeat, reallege, and reincorporate the allegations in the foregoing paragraphs as though fully set forth herein.

18. The FDA is an agency subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request and provide a lawful reason for withholding any other materials as to which it is claiming an exemption.

19. Plaintiffs have exhausted all administrative remedies under FOIA as to the June 2018 Request, because the FDA failed to make a determination in regard to the Request within 20 business days. *See* 5 U.S.C. § 552(a)(6)(A), (C). The FDA also failed to make a determination within the extended timeframe set out in its November 2018 letter.

20. Accordingly, Plaintiffs are entitled to an order compelling the FDA to produce records responsive to the June 2018 Request.

COUNT II

21. Plaintiffs repeat, reallege, and reincorporate the allegations in the foregoing paragraphs as though fully set forth herein.

22. The FDA is an agency subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request

and provide a lawful reason for withholding any other materials as to which it is claiming an exemption.

23. Plaintiffs have exhausted all administrative remedies under FOIA as to the October 2018 Request, because HHS failed to make a determination in regard to the appeal of the denial of the Request within 20 business days. *See* 5 U.S.C. § 552(a)(6)(A), (C).

24. Accordingly, Plaintiffs are entitled to an order compelling the FDA to produce records responsive to the October 2018 Request.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

25. Declare that the documents sought by the June 2018 and October 2018 Requests, as described in the foregoing paragraphs, are public under 5 U.S.C. § 552 and must be disclosed;

26. Order the FDA to undertake an adequate search for the requested records and provide those records to Plaintiffs within 20 business days of the Court's order;

27. Award Plaintiffs the costs of this proceeding, including reasonable attorney's fees, as expressly permitted by FOIA; and

28. Grant Plaintiffs such other and further relief as this Court deems just and proper.

Dated: New York, New York
May 22, 2019

/s/

David E. McCraw
Dana R. Green
Legal Department
The New York Times Company
620 Eighth Avenue
New York, NY 10018
Phone: (212) 556-4031
Fax: (212) 556-4634
E-mail: mccraw@nytimes.com

Counsel for Plaintiffs